January 31, 2025

Marzzan Lucas Jorge
% Jose Huerta
Consultant
Sanrubio, LLC
8345 Park Blvd, Apt 6310. Mailbox 289
Miami, Florida 33126

Re: K241193
Trade/Device Name: AGILIS - Multi-function Physical Therapy Table (Model: Plus, Pro and Basic.)
Regulation Number: 21 CFR 890.5880
Regulation Name: Multi-Function Physical Therapy Table
Regulatory Class: Class II
Product Code: JFB
Dated: January 3, 2025
Received: January 3, 2025

Dear Jose Huerta:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Amber T. Ballard -S

Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241193

Device Name
AGILIS - Multi-function Physical Therapy Table (Model: Plus, Pro and Basic.)

Indications for Use *(Describe)*
AGILIS is a Multi-function physical therapy tables intended for medical purposes that consists of a motorized table which can be equipped to provide patients with powered distraction, powered flexion, and muscle relaxation therapy. Neither device provides heat therapies.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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ALTHERY

510(K) SUMMARY

January 31, 2025

Administrative information

Applicant

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Device name and classification

Type of Submission:	Traditional
Device's Trade Name:	AGILIS - Multi-function Physical Therapy Table
Device's Common Name:	AGILIS - Multi-function Physical Therapy Table
Classification Name:	Table, Physical Therapy, Multi-Function
510(k) Submitter:	MARZZAN LUCAS JORGE
Regulation Number:	21CFR 890.5880
Device Class:	Ⅱ
Classification Panel:	Physical medicine
Product Code:	JFB

Predicate information

510(K) number	K063034
Applicant	HILL LABORATORIES CO.
Model name	AIR-FLEX WITH AUTO-DISTRACTION
Classification name	Table, Physical Therapy, Multi-Function
Classification Panel:	Physical medicine
Regulation Number:	21CFR 890.5880
Device Class:	II
Product Code:	JFB

Indications for Use

AGILIS is a multi-function physical therapy tables intended for medical purposes that consists of a motorized table which can be equipped to provide patients with powered distraction, powered flexion, and muscle relaxation therapy. Neither device provides heat therapies

Device Description

The AGILIS multifunction physiotherapy table and its line of models (Plus, Pro and Basic) are devices intended to provide patients with powered distraction, powered flexion, and muscle relaxation therapy. Neither device provides heat therapies.

The devices of the AGILIS line are made up of different modules articulated with each other, which provide movements and regulations for the manipulations carried out by the professional. The movements are divided according to the type of operation: manual or electric.

Manual operation systems:

- Headpiece.
- Extension of feet.
- Drops.
- Dorso - lumbar release/breakaway
- Lateral Flexion.

Electrical operating systems:

- Horizontal elevation.
- Flexion of the lower limb sector.
- Extension or linear movement of the lower limb sector (distraction/traction).

Physiotherapy table models:

- *AGILIS "PLUS" multifunction physiotherapy table*, is the most complete model in the line of physiotherapy tables and has the following features:

- Lifting system with 24Vdc electric motor/actuator.
- Flexion system with 24Vdc electric motor/actuator.
- Lumbar distraction system with 24Vdc electric motor/actuator.
- Manual drops system.
- Manual adjustment of the articulated headpiece.
- Manual regulation of the dorso-lumbar release/breakaway.
- Manual regulation of leg length.
- Manual regulation of lateral flexion movement.
- Wheel system for transportation.

- AGILIS "PRO" multifunction physiotherapy table, only differs from the "Plus" model in that the lifting system is compensated by mechanical springs, which allows the time to raise the equipment to be shorter by having to exert less effort.

- AGILIS "BASIC" multifunction physiotherapy table, this configuration is a simplification of the previous configurations since it does not have a lifting system. It has the following features:

- Flexion system with 24Vdc electric motor/actuator.
- Lumbar distraction system with 24Vdc electric motor/actuator.
- Manual adjustment of the articulated headpiece.
- Manual regulation of the dorso-lumbar release/breakaway.
- Manual regulation of leg length.
- Manual regulation of lateral flexion movement.
- Manual drop system
- Fixed height

Dimensions:

- Physiotherapy table: 65" to 73" length, 23" width – optional 26".
- Headpiece: width 18" wide x 13" long. Made up of 3 pieces: 1 (one) central piece to support the patient's face and 2 (two) sides.
- Upper dorsal sector: 23" wide x 6.5" long.
- Lumbar back sector: 23" wide x 9" long.
- Pelvic sector and leg: 23" wide x 17" long and 23" x 6" long.
- Extendable sector: 23" wide x 9" long.

Components:

- Electrical source, model: MEA-250A24C.

Accessories:

- Set of belts and fastenings.
- Removable Armrest: This optional component consists of two armrests measuring 23.5" inches x 6 inches each and an additional upholstery section measuring 23 inches' x 6 inches.
- Side supports: Comprising two lateral supports (right and left) and two belts with a fixed end and an adjustable end.

Contraindications:

Use of the chiropractic table is contraindicated in the following situations:

- Patients under 22 years of age or weighing less than 100 lbs., where the force applied may be inappropriate for their body weight or developmental stage.
- Patients with severe osteoporosis, where bones are highly fragile and susceptible to fractures under mechanical force.
- Recent spinal surgery or spinal fractures, where mechanical adjustments or traction could disrupt healing or cause further injury.
- Tumors, infections, or fractures of the spine, where mechanical force could exacerbate the condition or cause undue stress to affected areas.
- Severe psychiatric disorders, such as depression where the condition could affect the patient's ability to cooperate during treatment or pose a safety concern.
- Liver and renal dysfunction, which may limit the patient's ability to recover or handle physical therapy.
- Patients with cardiac failure, where high-force adjustments may pose a risk to cardiovascular health.
- Pregnancy, especially in later stages, where mechanical traction or significant force on the abdominal area should be avoided.
- Patients with a history of cerebrovascular accidents (CVA) or myocardial infarctions within the last six months, where the application of physical stress may trigger complications.

Additional exclusion criteria include patients with LBP caused by tumors, infections, or fractures; those with previous back surgery; severe osteoporosis; psychiatric disorders (e.g. schizophrenia); liver or renal dysfunction; pregnancy; medication for cardiac failure; a history of CVA or myocardial infarction within six months; and those deemed unsuitable for traction by the attending physician.

As always, consult the patient's overall medical history and perform a thorough evaluation before beginning chiropractic therapy, and adjust treatment parameters accordingly to ensure both safety and efficacy.

Substantial equivalence comparison

Feature	Proposed Device	Predicate Device	Comparison
General characteristics			
Name	AGILIS	AIR FLEX with auto distraction	-
510(K) number	K241193	K063034	-
Class	II	II	Same
Product code	JFB	JFB	Same
Regulation	21 CFR 890.5880	21 CFR 890.5880	Same
Indications for Use	AGILIS is a multi-function physical therapy tables intended for medical purposes that consists of a motorized table which can be equipped to provide patients with powered distraction, powered flexion, and muscle relaxation therapy. Neither device provides heat therapies	The Air-Flex is a multi-function physical therapy table intended for medical purposes that consists of a motorized table which can be equipped to provide patients with powered distraction, powered flexion, and muscle relaxation therapy.	Same
Dimensions	Length 65” to 73” - width 23”, optional 26”.	Length 68” to 77” - width 24”, optional 27”. *Not declared in version I of this device, the measurements represented here were obtained from version II of the predicate device.*	Similar - The difference between the specification does not generate or modify the risks already established for this type of devices.
Product weight	330 lbs. without accessories	250 lbs.	Similar - The difference between the specification does not generate or modify the risks already established for this type of devices.
Materials	Vinyl	Vinyl	Same
Technological characteristics			
Electrical operation	24Vdc	24 Vdc	Same
Abdominal decompression	Yes	Yes	Similar - The difference between the specification does not generate or modify the risks already established for this type of devices.
Headpiece	Manual and mechanical operation system with multiple positions: prone, supine, and lateral position.	Manual or air-drop drive system	Similar - The difference between the specification does not generate or modify the

	Range of motion: Flexion: 20 degrees when in the uppermost position. Extension: 15 degrees when in the lowest position	Angle: 30° positive or negative. Movements: Drops, lateral flexion, and flexion.	risks already established for this type of devices.
Lateral motion	Free movement of 15° to each side. It can also be left fixed every 2.5°. Lateral Flexion with locking mechanisms.	Rotation and Lateral Flexion with locking mechanisms, up to 21°.	Similar - The difference between the specification does not generate or modify the risks already established for this type of devices.
Arm rest	Yes	Yes	Same
Feet extension	Length 65” a 73”,	Length 68” to 77” *Not declared in version I of this device, the measurements represented here were obtained from version II of the predicate device.*	Similar - The difference between the specification does not generate or modify the risks already established for this type of devices.
Emergency stop	2 emergency stops (user and operator) Visual alarm system	2 emergency stops (user and operator) Alarm system	Similar - The difference between the specification does not generate or modify the risks already established for this type of devices.
Drop system	6 drops: 2 cervical, 1 upper dorsal, 1 lumbar dorsum, 1 sacral, and 1 ankle. Manual operation	5 drops: thoracic, lumbar, pelvic, cervical. Pneumatic actuation	Similar - The difference between the specification does not generate or modify the risks already established for this type of devices.
Traction system	Electric actuators system	Pneumatic actuators system	Similar - the differences are analyzed in the following paragraph “substantial equivalence (SE) - rationale”
Flexion system	Electric actuators system	Pneumatic actuators system and manual flexion system	Similar - the differences are analyzed in the following paragraph “substantial

			equivalence (SE) - rationale"
Lifting capacity - with lying patient	450 pounds	450 pounds	Same
Height regulation:	Agilis Plus:21.5" – 29.5" Agilis Pro: 21.5" – 31" Agilis Care: fixed height in 20", 25" or 30"	21.5"-28" or 22.5"-29"	Similar - The difference between the specification does not generate or modify the risks already established for this type of devices.
Display	Touchscreen Control	Touchscreen Control	Similar - The difference between the specification does not generate or modify the risks already established for this type of devices.
Pedals	Height Pedal	Corded Height Pedal Optional Rocker Foot Pedal Power Foot Strips for activating Airdrops (optional) Air-Pressure Foot Pedal 1	Similar - The difference between the specification does not generate or modify the risks already established for this type of devices.
Air system	Not include	Air Tank Power and Air-Drop Control Panel	Different - The difference between the specification does not generate or modify the risks already established for this type of devices.
Accessories	Set of belts and fastenings. Removable Armrest Side Supports	Seatbelt Ankle straps	Similar - The difference between the specification does not generate or modify the risks already established for this type of devices.
Safety and performance testing			
Non-clinical testing	EN/IEC 60601 -1:2005 + AMD1:2012 + AMD2:2020 - Medical Electrical Equipment - Part I: General Requirements for Basic Safety and Essential Performance.	IEC 60601-1 Medical Electrical Equipment- Part 1: General Requirements for Safety	Similar

	IEC 60601-1-2:2014 +AMD1:2020- Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.		

Substantial equivalence (SE) - rationale

The main features and differences found between the devices are summarized below:

- The proposed device shares the same or similar basic characteristics and the same general use in physical medicine as the predicate device.

- The product code (JFB) and Indications for Use between the predicate device and the proposed device is the same: multi-function physical therapy table intended for medical purposes that consists of a motorized table which can be equipped to provide patients with powered distraction, powered flexion, and muscle relaxation therapy.

- The proposed device operates on AC to bring the motors voltage to 24 volts DC in the same manner as the AIR FLEX predicate device cleared under K063064. The power is through an external source for medical use.

- The proposed device, as the predicate, allows the automatic cycle of the distraction (traction) and flexion process in a specific period of time with multiple configurable parameters. These automatic cycles are controlled by a microprocessor on both devices.

- The proposed device, as the predicate device, has an emergency stop mechanism accessible to the patient in case the patient feels discomfort. On both devices this mechanism interrupts the operation, and the patient cannot reactivate the operation by himself, the operation must be reactivated by the qualified operator.

- The materials used in the construction of the device, including the structure and upholstery, are similar.

- The predicated device, as the proposed device, has an alarm system that is activated when the emergency stop is activated; none of the devices allow the patient to reactivate the operation of the device without intervention of the professional operator. The predicate device has an audible alarm, while the proposed device has a visual alarm system through the device screen. This difference does not affect the safety and effectiveness of the device.

Main differences between technological features:

- The predicated device uses pneumatic actuators for traction and flexion of the device components, while the proposed device uses electric motors to achieve the same result.
  This difference in the proposed device is for the purpose of minimizing the dependence of the actuator systems on each other, minimizing the possibility of a generalized failure occurring in all the systems

in the tables, leaving it unusable and avoiding the potential failure of the established parameters and that could potentially generate sudden movements due to changes in loading conditions. By working with electric actuators, the independence of each actuator system is achieved, avoiding a generalized failure and at the same time guaranteeing that without power, the load cannot generate unexpected movements.
This difference does not affect the safety and effectiveness of the device.

- The predicated device has a system of 5 drops located in the thoracic, lumbar, pelvic and 2 cervical areas, the proposed device includes 6 drops located as follows: 2 cervical, 1 upper dorsal, 1 lumbar dorsum, 1 sacrum, and 1 ankle. The proposed device adds an ankle drop, which has the same operating mechanism as cervical drops, the risks being those already known, analyzed, and minimized for this type of devices.
  This difference does not affect the safety and effectiveness of the device.

Therefore, the proposed device is considered by MARZZAN LUCAS JORGE to be Substantially Equivalent to the predicate device.

Non-Clinical Testing Summary

The Multi-function Physical Therapy Table – Model AGILIS was tested to evaluate its safety and effectiveness based on the following standards:

Electrical Safety, Electromagnetic Compatibility:

- EN/IEC 60601 -1:2005 + AMD1:2012 + AMD2:2020 - Medical Electrical Equipment - Part I: General Requirements for Basic Safety and Essential Performance.

- IEC 60601-1-2:2014 +AMD1:2020- Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

Performance Standard

Since there are no mandatory standards for these type of devices, “MARZZAN LUCAS JORGE” decided to adhere to the FDA guidelines outlined in the guidance document ‘Recommended content and format of non-clinical bench performance testing information in premarket submissions – Guidance for industry personnel and the Food and Drug Administration’, and has performance Safety Testing – Load Application (static and dynamic) and Efficacy Testing – Functional Analysis tests on the AGILIS multifunction physiotherapy tables.

Furthermore, in order to guarantee the correct functioning, safety and effectiveness of the physiotherapy tables, an operational control is carried out on 100% of the manufactured tables before their release to the market, according to the procedures described in this submission.

Software

After a comprehensive evaluation that considered: the description of the device, its Indications for Use, software analysis, known or foreseeable software hazards, and dangerous situations associated with the device, including those that could result from misuse, whether intentional or not, and the impact that these

could have on the patient or user, it was determined that the Software documentation level evaluation is Basic Documentation.

The software information is provided in accordance with FDA guidance "*Content of Premarket Submissions for Device Software Functions"*.

Animal Study

No animal studies were considered necessary and performed.

Clinical Studies

No clinical studies were considered necessary and performed.

Conclusion

The proposed device is substantially equivalent to the currently marketed and predicate device in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

Additionally, substantial equivalence was demonstrated through the non-clinical performance, which complied with the requirements specified in the international and FDA-recognized consensus standards, IEC 60601-1, IEC 60601-1-2, and bench testing.

The results of these tests demonstrate that the proposed device meets the acceptance criteria and is adequate for this Indications for Use. The comparison of technological characteristics, non-clinical performance data, electrical safety and electromagnetic compatibility testing demonstrates that the device is substantially equivalent to the previously cleared predicate devices.